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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,353

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Lennart Jonsson

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP

901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

DEAK, LESLIE R

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,353	Applicant(s) JONSSON ET AL.	
	Examiner LESLIE R. DEAK	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-22 and 24-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-22 and 24-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/09/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 6 and 7 recite the limitation "the component" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim, since the referenced component does not appear in the parent claims. For the purposes of examination, the Examiner is assuming claim 6 to depend from claim 3.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-8, 10-22, and 24-35, are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,807,258 to Cimochowski et al in view of US 6,484,586 to Dutoit et al.

In the specification and figures, Cimochowski discloses the apparatus substantially as claimed by Applicant. With regard to claims 1, 12, 13, 16, 17, 19, 21,

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24, 26, 28-31, 33, and 34, Cimochoowski discloses a sensor for monitoring the condition of a vascular graft (which may be used as part of an extracorporeal circuit) comprising at least one pressure sensor or transducer that is configured to be energized by a first source of energy (such as radio frequency) external to the patient's body, a second transducer that receives external energy and transmits information about the pressure change to an external receiver (see, generally, columns 6, 8).

Cimochoowski fails to disclose that the source of energy is an alternating electromagnetic field. However, Dutoit discloses a differential pressure transducer that uses an alternating electromagnetic field to energize the induction coils in order to measure the deflection of a measurement membrane in order to measure pressure (see at least column 11, lines 45-60). This apparatus is low-cost and easy to manufacture (see column 2, lines 20-27). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to use the alternating electromagnetic field as disclosed by Dutoit in the pressure measurement apparatus disclosed by Cimochoowski, in order to provide an economical pressure measurement device, as taught by Dutoit. With regard to Applicant's recitation that at least part of the extracorporeal circuit is disposable, it is the position of the Examiner that a tubing set used in extracorporeal circulation is capable of being disposed, meeting the limitations of the claims.

With regard to claims 4 and 32, Cimochoowski discloses that the apparatus may comprise a capacitor that stores energy in order to allow the device to be energized away from the energy source.

With regard to claims 2, 5-8, 10, Dutoit discloses that the sensor may comprise a compressible container (space 211 surrounded by walls 203, 204, 206) capable of indication pressure through deflection of a separating membrane 250 upon which component 270 is disposed (see FIG 2).

With regard to claim 3, Dutoit discloses that the apparatus comprises an inductor that forms a resonance circuit that varies with the movement of the membrane (see column 9, lines 51-67).

With regard to claims 14, 15, and 35, the cited prior art suggest each structural element of the device set forth in claim 1 (see rejection above).

Chimochowski teaches that the device comprises a compressible container and is attached to the graft wall, but is silent as to the method of making and adhering. The claimed phrases “wherein the device is insert molded” and “wherein the sensor is glued or welded to a wall” are being treated as product by process limitations; that is, that the device is made by insert molding and attached by gluing or welding. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP § 2113.

Thus, even though Cimchowski is silent as to the process used to make the device and attach it to the graft, it appears that the product in Cimchowski would be the

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same or similar as that claimed; especially since both applicant's product and the prior art product is made of a compressible material and is attached to a tube.

With regard to claims 11, 18, 19, 25, 27 Applicant is setting forth the intended use of the claimed apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, it is the position of the Examiner that the cited prior art may be programmed to use atmospheric pressure as the reference pressure and that it may be used during fluid management such as dialysis.

6. In the alternative to the rejection presented above, claims 1, 10-22, 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,807,258 to Cimochoowski et al in view of US 5,873,840 to Neff et al.

In the specification and figures, Cimochoowski discloses the apparatus substantially as claimed by Applicant. Cimochoowski discloses a sensor for monitoring the condition of a vascular graft (which may be used as part of an extracorporeal circuit) comprising at least one pressure sensor or transducer that is configured to be energized by a first source of energy external to the patient's body, a second transducer that receives external energy and transmits information about the pressure change to an external receiver (see, generally, columns 6, 8).

Cimochoowski fails to disclose that the source of energy is an alternating electromagnetic field. However, Neff discloses a pressure measuring apparatus that

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comprises a resonator unit 22 that is energized with a waveform (or alternating field) from outside the apparatus by a transmitter 32, providing a low-risk way to measure pressure while the patient is ambulatory. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to use the alternating field as disclosed by Neff in the pressure measurement apparatus disclosed by Cimochoowski, in order to provide a low risk pressure measurement device, as taught by Neff. With regard to Applicant's recitation that at least part of the extracorporeal circuit is disposable, it is the position of the Examiner that a tubing set used in extracorporeal circulation is capable of being disposed, meeting the limitations of the claims.

Response to Arguments

7. Applicant's arguments, filed 9 June 2009, with respect to the rejection(s) of the pending claim(s) under Crozafof and Esch have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Cimochoowski, Dutoit, and Neff, as presented above.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
11 August 2009